REMARKS

This amendment is responsive to the Office Action dated Feb. 9, 2004.

Applicant notes with appreciation the indication of allowability of claims 8-12 subject to being rewritten in independent form and to overcoming the rejections made under 35 USC 112, second paragraph. Applicant also notes the indication of allowability of claim 15, subject to overcoming the rejections made under 35 USC 112, second paragraph. By this amendment, the claims have been extensively amended to define the invention with greater particularity and eliminate any vagueness or indefiniteness.

Claims 1, 2 and 14 were rejected under 35 U.S.C. 102(b) as anticipated by the patent to Walt et al, U.S. 6,023,540. This rejection is respectfully traversed.

Walt et al discloses a complex of coated micro-spheres mounted inside a number of microscopic sized wells located in the end of a bundle of optic fibers. The microscopic wells are formed by etching the end of the fiber bundle, which produces a minute depression or well in the end of each fiber in the bundle. Each bead is coated with or contains a "chemical functionality" for a respective known analyte. The coated beads are introduced into the formed wells and are then treated so that they swell up in size to thereby physically frictionally anchor each coated bead to the side of a respective well. With the beads thusly attached, the end of the optical fiber bundle effectively forms a super sensor containing an array of individual sensors.

By dipping the end of the optic fiber bundle into a liquid sample that contains a target analyte, the one bead in the collection that contains the coating that detects that target analyte produces a reaction, such as by emitting a code, a unique fluorescence, and/or by locating the position of the emitting bead. By analyzing the emitted energy (e.g.correlating the finding with a listing of analytes or determining which bead produced the reaction), the particular analyte that was detected is identified.

If multiple beads in the sensor emit energy, then multiple target analytes are present, and the analyses of the emission identifies each of those analytes. Although the disclosure of Walt et al appears to be directed to targeting chemicals, at column 9

lines 60-67 through column 10, lines 1-3, Walt indicates that Immuno-based microsphere sensors "have been demonstrated" for diagnostics of bacterial, virus, fungal, mycoplasmal, protozoal, Rickettsial substances, inferring that the disclosed invention can also be used to detect those substances. However, Walt is silent on the bead coatings for those target substances and does not provide a specific example of the necessary coating or specifics of the procedure and testing.

The Examiner correctly notes that Walt determines the presence of an individual analyte from amongst a plurality of analytes. However, the rejection further asserts that Walt discloses "collectively" determining the results and determining an analyte of interest. Applicant respectively disagrees with the foregoing factual assertion, which applicant finds ambiguous and possibly misleading.

Applicant was unable to locate any description in the Walt patent showing or teaching of "collectively determining the results" and is unable to determine the meaning of that phrase. Walt et al. teaches "determining the results," but not collectively determining the results.

Specifically, applicant doesn't understand the meaning of the term collectively as used in the rejection of claim 1 in the context of the Walt et al system. The fiber bundle in Walt contains a large number of sensors and each of those sensors is designed to detect a respective one of a large number of target analytes. That fiber bundle constitutes a "super" sensor, so to speak. When the fiber bundle is dipped into the liquid specimen each of those multiple sensors goes to work and checks the specimen for a respective analyte. If one (or more) of the different target analytes is present, then one (or more) of the multiple sensors will chemically react. By inspecting the sensors with appropriate equipment, the skilled operator is able to check the emissions and determine which of the multiple sensors underwent a reaction, and, knowing the correlation between a specific sensor (e.g. coated bead) or emissions and the target analyte that is associated with that coated bead (or emission), the operator is able to determine the number and identity of different target analytes present in the sample. That procedure cannot fairly be described as "collectively" determining the results. That action is simply determining the results.

As one appreciates, the foregoing determination required by the described test takes some skill on the part of the test operator. Applicant's system conducts a number of tests, but the test operator doesn't require special skills or knowledge. The operator knows that if particular ones of the N tests that are performed prove positive, through a pre-charted correlation, the target bioagent is identified. The foregoing procedure is explained at length in the specification. A review of the specification is strongly recommended.

Claim 1 recites that "*the collective result of said plurality of N detection processes identifies an individual one of said plurality of 2^N-1 bioagents.*" Clearly that's not what the Walt et al. patent describes or suggests. In the system of the Walt et al. patent each individual sensor (e.g. bead) identifies an individual analyte (e.g. bioagent). Further, although the sample in Walt may be said to be effectively divided into N parts, which isn't a correct characterization in applicant's view, any such division is made to detect any of N different bioagents, not one of 2^N-1 different bioagents.

Further, claim 1 also recites: "*each of said separate detection processes of said plurality of N detection processes for detecting the presence of any bioagent within a defined collection of bioagents found within said plurality of 2^N–1 different bioagents, said defined collection of bioagents detected by any one of said separate detection processes in said plurality of N detection processes being different from the collection of bioagents that is detected by any other of said separate detection processes in said plurality of N detection processes; said collections of bioagents in total including said entire plurality of 2^N–1 different bioagents.*" That relationship is not shown or taught in Walt.

Applicant understands that in order for a reference to anticipate a claim, the reference must show each and every element recited in the claim and any relationship prescribed in the claim for the recited elements. For the foregoing reasons, applicant submits that Walt et al does not anticipate claim 1 under 35 USC 102 (b). Applicant respectfully requests the Patent Office to reconsider and withdraw the rejection of claim 1 over Walt et al

Claim 2 depends from claim 1 and incorporates all of the recitations in claim 1. Applicant refers to and incorporates herewithin the discussion of the rejection of claim 1.

For the foregoing reasons, applicant submits that claim 2 cannot be anticipated by the application of Walt et al. Applicant respectfully requests the Patent Office to reconsider and withdraw the rejection of claim 2 on Walt et al.

Claim 14, which is of broad scope, may be considered further. The claim claims a method of testing for bioagents, comprising the steps of:

dividing a sample into at least N portions; and

performing a plurality of N tests for bioagents concurrently on respective portions of said sample to determine the existence of any one of a plurality of 2^N-1 bioagents in said sample, where N is an integer greater than 1.

Thus, as brought out in the specification, if N is three, then the number of potential different bioagents that may be detected and identified in only three tests is seven. If N is four, then the number of such bioagents that may be detected and identified in only four tests is fifteen. The foregoing testing defined in claim 14 is markedly different from the system of Walt. Walt tests any number of bioagents in a single pass. That is, if you want to test for any of fifteen different bioagents in a sample, then include a sensor for each bioagent. That is, in Walt there is a one to one correspondence between the number of bioagents and the number of sensors. And, since each sensor is equivalent to a "test", then there are N tests for N different bioagents. Applicant's system requires, at most, only four tests to accomplish the same feat.

Because all the tests are conducted simultaneously in Walt , one may view that prior art system as a faster, more efficient, easier to use system than that of the present invention, and, hence, may view the claimed system disclosed by applicant to be a step backward in the art. However, the jury is still out on the subject, as such systems of Walt are not known to applicant to be found in practice and detection out in the field, such as for bio-terrorism agents or bio-warfare agents, introduces requirements that favor a scheme described in applicant's specification. At some point, if ever, when all those systems are introduced to the marketplace, the marketplace, in practice the best judge of what is the best system, will decide the system that is best overall.

Claims 1-6 and 14 were rejected under 35 U.S.C. 102(e) as anticipated by the Published application to Shipwash, U.S. 2002/0058273. This rejection is respectfully traversed.

The publication to Shipwash discloses a method and system for biomolecular recognition of amino acids and for protein sequencing.

According to a publication by Shipwash, all proteins from bacteria to man are synthesized from the same set of 20 amino acids. Each amino acid has one specific synthetase and one or more isoaccepting tRNA. The enzymes are highly selective for the amino acids they bind, and even more selective in their attachment of the amino acids to their specific tRNAs. The basis of the method for amino acid analysis is that each synthetase and/or one isoaccepting tRNA specific for each amino acid is separated into a different chamber or immobilized onto a separate transducer or a spatially separated zone and the reactions catalyzed by the 20 synthetases are monitored using a position-sensitive detector.

Shipwash effectively divides the sample between separate channels and each channel is checked for a particular one of the (twenty) amino acids. In effect, each channel constitutes an individual sensor for a particular one of the different amino acids

The rejection asserts that Shipwash disclose a method of determining the existence of and identifying an "analyte of interest." However, the Shipwash publication states that the search is for one or more of twenty different amino acids. The rejection further asserts that the Shipwash publication discloses applying a sample to a ...device, which divides the sample "into an array of reaction chambers (Fig. 5B)." However, the publication states that the sample is "flowed" through "parallel channels", not deposited in chambers.

In taking liberty with the language, it appears that the Patent Office viewed the disclosure of the Shipwash patent through "rose colored glasses" taken through hindsight from the applicant's disclosure. In so doing the Patent Office seeks to construct the claimed method in Shipwash through judicious choice of semantics. Applicant submits that the reasoning of the Patent Office fails, and that Shipwash does

not and cannot be said to anticipate any of the cited claims within the meaning of 35 U.S.C 102.

Claim 1 is a method of determining the existence of a single one of many different bioagents in a sample, not, as in the Shipwash publication, individual parallel determinations of the sequential identity of amino acids in a protein of interest. Shipwash does not collectively detect amino acids and doesn't teach collective detection of amino acids or bioagents. The identity of a bioagent is the collective result of the plurality of tests in the method set forth in applicant's claim 1. By contrast, the identity of an amino acid is the result of the individual concurrent tests in Shipwash. Claim 1 recites that "*the collective result of said plurality of N detection processes identifies an individual one of said plurality of 2^N-1 bioagents.*" Clearly that's not what the Shipwash publication describes or suggests. In the system of the Shipwash publication each individual sensor identifies an individual analyte and detects any of N different amino acids, not one of 2^N-1 different bioagents.

Further, claim 1 also recites: "*each of said separate detection processes of said plurality of N detection processes for detecting the presence of any bioagent within a defined collection of bioagents found within said plurality of 2^N–1 different bioagents, said defined collection of bioagents detected by any one of said separate detection processes in said plurality of N detection processes being different from the collection of bioagents that is detected by any other of said separate detection processes in said plurality of N detection processes; said collections of bioagents in total including said entire plurality of 2^N–1 different bioagents.*" That relationship is not shown or taught in Shipwash.

Applicant understands that in order for a reference to anticipate a claim under 35 U.S.C 102, the reference must show or teach each and every element recited in the claim and any relationship prescribed in the claim for the recited elements. For the foregoing reasons the disclosure of Shipwash is lacking, and, applicant submits, that the Shipwash publication cannot anticipate the method of claim 1. Applicant respectfully requests the Patent Office to reconsider and withdraw the rejection of claim 1 on Shipwash.

Claims 2–6 depend, directly or indirectly, from claim 1 and incorporate all of the recitations in claim 1. Applicant refers to and incorporates here within the discussion of the rejection of claim 1. For the foregoing reasons, applicant submits that claims 2-6 cannot be anticipated by the application of Shipwash. Applicant believes claims 2-6 also defines patentable subject matter. Applicant respectfully requests the Patent Office to reconsider and withdraw the rejection of claims 2-6 on Shipwash.

Claim 14, which is of broad scope, may be considered further. The claim claims a method of testing for bioagents, comprising the steps of:

dividing a sample into at least N portions; and

performing a plurality of N tests for bioagents concurrently on respective portions of said sample to determine the existence of any one of a plurality of 2^N-1 bioagents in said sample, where N is an integer greater than 1.

Thus, as brought out in the specification, if N is three, then the number of potential different bioagents that may be detected and identified in only three tests is seven. If N is four, then the number of such bioagents that may be detected and identified in only four tests is fifteen. The foregoing testing defined in claim 14 is markedly different from the system of Shipwash. Shipwash tests any number of amino acids in a single pass. That is, if you want to test for any of fifteen different amino acids in a sample, then include a sensor for each amino acid. That is, there is a one to one correspondence between the number of amino acids and the number of sensors. And, since each sensor is equivalent to a "test", then there are N tests for N different amino acids. Applicant's system requires only four tests to accomplish the same feat with bioagents.

Because all the tests are conducted simultaneously in Shipwash , one may view that prior art system as a faster, more efficient, easier to use system than that of the present invention, and, hence, may view the claimed system disclosed by applicant to be a step backward in the art. However, the jury is still out on the subject, as such systems are not known to be found in practice for detection of bioagents in the field or in clinics. Rather the utility of Shipwash appears limited to research applications. At some point. if ever, when all those systems are introduced to the marketplace, the

marketplace, which is the best judge of which is the best system in practice, will decide the system that is best overall.

Claims 1-15 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) The Patent Office asserts that the phrase "The method" at the commencement of claim 1 lacks sufficient antecedent. The claim has been amended to recite "A method," which should correct any asserted lack of antecedent.

(2) The Patent Office asserts that the recitation of a "plurality of 2^N-1 bioagents" is vague and indefinite. The Patent Office reasons that the recitation does not make clear whether the claim calls for identification of many of the same type of bioagents or for different types of bioagents. Applicant respectfully disagrees.

There is only one possible interpretation in applicant's view. Applicant believes the specification is more than adequate to give the proper meaning to the recited phrase. The assertion that the applicant is actually keeping a count of the number of "bugs" of a single type, applicant submits, is totally out of context with the content of the patent application. For that reason, Examiner's proposed interpretation is believed to be unreasonable. Notwithstanding the adequacy and definiteness of the cited recitation, applicant amended the recitation to include the word "different." That change, hopefully, should make clear to everyone that different types of bioagents are intended in the legal definition of applicant's new method presented in claim 1.

(3) The Patent Office asserts that the recitation of "plurality of N detection processes" is vague and indefinite. The Patent Office reasons that the recitation lacks clarity as to whether application is using many different detection process(es) or many of the sample detection process(es) to detect a bioagent, querying as to whether, as example, one detection process is a raman spectroscopy detection process and a second detection process (is) an Immunoassay detection process. Applicant respectfully disagrees.

As Examiner has likely gleaned from re-reading the specification of the application, the preferred embodiment uses a single "kind" of detection process, the

ELISA procedure, to detect a bioagent. However, as those skilled in the art appreciate, the new method is not so limited, except to require recognition molecules. See paragraph [0037] of the specification. That detection process is preferred because a single procedure appears to be most efficient and requires less training of the operator of the process. If one were to use N different processes that would require the operator to stock N different pieces of equipment and have training to operate N different processes. Although such would accomplish the claimed method, it's pretty clear that such an alternative embodiment is grossly inefficient, and, hence, less preferred. If one wishes to use N different processes, notwithstanding the obvious inefficiency, with each of those different processes being set to check for bioagents that fall in a collection of bioagents as categorized in and taught by the specification, so be it. Because the foregoing relates to the scope of the claimed method, applicant submits that the recitation is proper, appropriate and not vague or indefinite. Applicant respectfully requests that any rejection based on the foregoing asserted indefiniteness be reconsidered and withdrawn.

(4) The Patent Office reasons that the recitation in claim 1 of "employing" is vague and indefinite because Examiner thinks it unclear how a molecular interaction is used to identify a bioagent. Applicant respectfully disagrees. As defined in this application and related applications the action that occurs when an antibody binds to (e.g. attaches to) a bioagent is defined as a molecular interaction. See paragraphs [0004] and [0005] of the present application. Examiner fis invited to study the specification of the present application and well as application 09/837,946 to Sullivan et al, filed April 19, 2001 (now U.S. 6,562,209) that is referred to in the introduction of the specification. That's one source of prior knowledge of the interaction between an antibody and bioagent. Some have characterized that attachment as due to the mating physical shapes of the molecules of the two substances that cause the molecules to attach like pieces of a jig-saw puzzle. Applicant reminds the Patent Office, that the claim is a legal definition of the invention and is not intended to be a treatise of how to make the invention, physical phenomena or a fully detailed description of a practical embodiment. For the foregoing reason, applicant submits that the rejection is

groundless. In light of the foregoing, applicant respectfully requests that any rejection based on the foregoing asserted indefiniteness be reconsidered and withdrawn.

(5) The Patent Office further asserts that the recitation of "possessing a capability" in claim 1, also renders the claim vague and indefinite. The Patent Office queries as to whether the "separate detection processes detect a bioagent from a collection of known bioagents or not." And that the Patent Office cannot determine what capability the applicant (sic the claim) refers. In reply to the foregoing query applicants answer is yes, but collectively. The foregoing capability is explained at great length in the specification, and need not be here repeated. Applicant is uncertain of the basis of the Examiner's complaint. By this amendment, claim 1 has been amended to remove the identified phrase. As amended the claim now recites that a detection process is for detecting the presence of any bioagent within a defined collection of bioagents found within said $2^N - 1$ different bioagents. It is believed that the foregoing cures the indefiniteness that was perceived.

(6) The Patent Office states that the term "known bioagents" recited in line 11 of claim 1 is vague and indefinite because the claim does not make clear if those are the bioagents recited in line 2 of the claim or if they are different bioagents. The foregoing objection is not understood. It seems pretty clear from the claim to applicant that the bioagents recited in line 2 of the claim subsume the particular bioagents recited in line 11. That understanding should be very clear from the study of the description presented in the specification and the four examples given.

(7) The Patent Office further states that the term "known bioagents" is vague and indefinite. The reasoning given is a question: "Is applicant incorporating a standard or control into the method?" Applicant does not understand the reasoning and requests clarification. As a possible solution claim 1 is amended to delete "known.". However, as the Patent Office should appreciate, the term "known" is implicit even if unstated, since one skilled in the art cannot "identify" a bioagent that is unknown (and hence doesn't have a name). Consider the reference to Walt as example. How could Walt determine the fluorescent coding for an unknown agent. True, a code of fluorescence would be obtained, but that code would not correlate to any bioagent, since, as hypothesized, the bioagent is unknown. In that even one must isolate and examine the agent under a

microscope, give the agent a name so that it can be identified by name if ever encountered again and find some code or molecular interaction that may be used to detect the presence of that virus in a conventional test procedure, such as ELISA.

Recall the occurrence of the unknown virus in New Mexico some years ago that killed off healthy people who were exposed in relatively short order. That virus was isolated and inspected under a microscope, revealing something never before seen by scientists. The virus was new. The scientists gave the virus a name, the Hanta virus. They subsequently discovered that the virus originated in the feces of the deer mouse and was inhaled by those who swept the barn floor with a broom that atomized the powered mice crap. So initially, any test equipment can only identify (by name) only bioagents that have become known. The present method is no different. The virus must be known in order to provide a correlation of a physical property that is detected by the test equipment with a name of a bioagent.

(8) The Patent Office argues that claim 1 is further vague and indefinite because the Examiner finds lack of clarity as to why there is one more bioagent than a detection process and the detection process determines only one bioagent. Citing the case of N being equal to 2, the reasoning states "there are 3 bioagents and 2 detection processes to determine only one bioagent." "If (there are) three bioagents, how are they determined if only two separations are performed?" To the extent the foregoing rationale is understood applicant respectfully traverses the rejection. If N=2, the total number of bioagents possible is three different bioagents, not that there are three bioagents in the sample. See paragraphs 0041 through 0044. As concluded at the end of paragraph 0043 "*Thus, one is able to use two tests to determine the existence of any of the three kinds of bioagents if only a single one of the three bioagents being sought is present in the sample.*" It should be helpful to re-study that specification at this juncture.

An example with two processes is described on page 13 of the specification. The method is determines any one of three different bioagents possible (ie. assume N=2, then 2^N-1=3) in a sample. The first test (e.g. bead set A) is capable of detecting the presence of two bioagents in a sample, namely bioagents 1 and 2. The second test (e.g. bead set B) is capable of detecting the presence of two bioagents in a sample, namely bioagents 2 and 3. Note that the first and second tests, although different from

one another, are both able to detect the presence of bioagent 2 in a sample, so that there is some overlap. Next the sample is parsed in two and separate tests are run on the respective portions of the sample to look for the presence of one of the three candidate or target bioagents. The results of the two tests are then tabulated. If the first test (containing bead set A) is positive, but the second test (containing bead set B) is negative, then the chart (at page 13 line 12) identifies the bioagent as bioagent 1. If both tests are positive, then the chart identifies the bioagent as bioagent 2. If only the second test is positive, then the chart identifies the bioagent as bioagent 3. Hence we have two tests and are able to identify one of three possible bioagents. It is hoped that the enlightenment stemming from the foregoing repetition of a portion of the content of the specification will lead Examiner to study the specification and avoid unnecessary rejections based on 35 USC 112.

If by chance there are more than one different bioagents in the sample, then additional tests would need to be made. That additional testing is referred to in paragraphs 0045 and 0046 of the specification to which reference may be made. As there described if the two tests of beads A and B both returned a positive result, then only bioagent 2 should be present in the sample. However, both tests would return a positive result if both bioagents 1 and 3 are present concurrently in the sample, not bioagent 2. By running another test specifically for bioagent 2 only, a positive result shows that bioagent 2 is present; a negative result shows that both bioagents 1 and 3 are present in the sample.

The foregoing objection may alternatively suggest that the Examiner is suggesting that the claim recitation should repeat the description of the method invention presented in the specification and teach the method. Applicant respectfully disagrees with such a position and believes the claims are intended to be a legal definition of the invention.

For the foregoing reasons, applicant respectfully requests Examiner to reconsider and withdraw the foregoing rejection based on the cited indefiniteness discussed.

(9) The Patent Office reasons that the recitation of "multiple bioagents" in dependent claim 8 renders the claim vague and indefinite. Specifically, the rejection

queries whether the plurality of bioagents recited is that plurality recited in claim 1 or some other (undefined) plurality. Although the foregoing reasoning appears strained, Examiner's objection is easily cured by editing claim 8. Accordingly, claim 8 has been amended to recite said 2^N –1 different bioagents, making clear that the same group of bioagents is being referred to as in parent claim 1. Applicant believes the foregoing amendment cures the complaint.

(10) The reasoning applied to "multiple bioagents" in claim 8 is also applied in dependent claim 9. Applicant has resolved to the objection with the same solution. Examiner's objection is easily cured by editing claim 9. Accordingly, claim 9 has been amended to recite said 2^N –1 different bioagents, making clear that the same group of bioagents is being referred to as in parent claim 1. Applicant believes the foregoing amendment cures the complaint. The Examiner's reasoning also makes a passing reference to "see also deficiencies found in claim 10, 11. Presumably Examiner is referring to the same kind of objection. Accordingly claims 10 and 11 have been reviewed and amended in a like manner.

(11) The Patent Office asserts that claim 12 is vague and indefinite because of the use of the acronym and requires the terms to be defined in their first instance (in the claim). This objection is also indicated as being applicable to claim 15. By this amendment applicant has amended claims 12 and 15 to include the appropriate definition. That change cures the cited objection.

(12) The Patent Office reasons that claim 12 is vague and indefinite because claim 12 implies the use of a secondary antibody enzyme conjugate, and asserts that the claim does not recite a primary antibody, seemingly making the claim unclear if there is a primary antibody applied in the process. To the extent that the reasoning is understood, Applicant respectfully disagrees with the objection. First, the claim expressly recites secondary antibody enzyme conjugate molecules. Therefore, the statement that such is merely implied, applicant submits, is inaccurate. Second, there is no known requirement to recite a primary antibody, and/or the failure to recite a primary antibody does not make the claim vague and indefinite within the meaning of 35 USC 112. The claim recites an ELISA process, which, as is known, includes a primary antibody. See paragraph [0007], as example. Notwithstanding all of the foregoing,

applicant submits there is no reason why applicant must recite details in the legal definition presented in the claim, unless the prior art requires such a recitation, which is not the case here. Thus if a primary antibody is not recited, then, applicant submits, the claim should be examined against the prior art as if there was no primary antibody. Applicant submits that there should be no lack of clarity to one skilled in the art. Applicant respectfully requests that the foregoing reasoning be reconsidered and withdrawn and/or clarified.

(13) The Patent Office asserts that the phrase "The method" at the commencement of claim 15 lacks sufficient antecedent. The claim has been amended to recite "A method," which should correct any asserted lack of antecedent.

(14) The Patent Office asserts that the recitation in claim 15 of a "plurality of 2^N-1 bioagents" is vague and indefinite. The Patent Office reasons that the recitation does not make clear whether the claim calls for identification of many of the same type of bioagents or for different types of bioagents. Applicant respectfully disagrees for the reasons given in response to the like reasoning applied to claim 1, which is referred to and incorporated herewithin. Notwithstanding the adequacy and definiteness of the recitation, applicant has amended the recitation in claim 15 to include the word "different." Hopefully, that change should make clear that different types of bioagents is intended in the legal definition of applicant's new method presented in claim 15.

(15) The Patent Office reasons that the reference in line 10 of claim 15 to "the representative ELISA process" is vague and indefinite, stating the phrase lacks antecedent basis. Applicant respectfully disagrees. Applicant is unable to understand the objection. Specifically, applicant was unable to find any such phrase in claim 15. Should the Patent Office persist in the objection, applicant respectfully requests that Examiner recite the entire sentence in the claim to which Examiner is making reference. Additionally, applicant has significantly edited the claim and that editing may have corrected the particular wording that was of concern to Examiner.

(16) The Patent Office states that the phrase "is able to detect" is not a positive limitation, but only requires the ability to so perform, and emphasizes that the phrase does not constitute a "limitation in any patentable sense." Finally, the Patent Office queries "Does the ELISA process detect the bioagents or not."

Applicant is of the understanding that every recitation in a claim is considered in the interpretation of the scope of a claim, that is every recitation "counts." So if a recited device is required to have a characteristic or capability, applicant submits, that any device accused of infringement must include that characteristic or capability. Further applicant submits that the recitation of the detection capability of the ELISA process is in fact a positive recitation, which is required. The claim recitations are not required to limit the scope of the claim but to define the method invention. Notwithstanding, by this amendment, claim 15 has been extensively edited and now recites the function of the recited element more forcefully. It is believed that such cures the objection.

The answer to Examiner's query is affirmative. See, as example, paragraph [0055] of the specification of the application. Each of the ELISA processes detects at least one kind of bioagent. If the bioagent in the sample is one that is detected by one or more of the individual ELISA procedures, then those ELISA procedures collectively detect the presence of that bioagent. Because most of the ELISA procedures are capable of detecting more than one kind of bioagent, those individual ELISA procedures, although detecting the presence of the bioagent, cannot identify the bioagent. The identification of the bioagent comes from the collective result of all ELISA procedures. The foregoing is described at length in the specification. With the present method, progressively more (and more) information about the sample is gained as more (and more) tests are performed.

(17) The Patent Office reasons that claim 15 rendered vague and indefinite due to the recitation in line 11 of the phrase "possessing a capability." The Patent Office queries "does the ELISA processes detect a bioagent from a collection unique bioagents or not?" and that query is followed by the statement that the particular capability being referred to is unclear. Applicant refers to the discussion presented in the preceding paragraph (16), which is incorporated herein. Applicant also refers to paragraph [0055] which describes collections. As Examiner should find from the present specification, the collections (of different primary antibodies) are unique (e.g the collections have different constituents) but the primary antibodies are not necessarily unique (e.g. a constituent antibody of one collection may also be found in another collection), and, in most cases are not unique.

(18) Claim 15 is further asserted to be vague and indefinite because the recitation of "unique collection" is unclear. The Patent Office states that it is unclear how the bioagents are unique. Applicant does not understand the reasoning given, because applicant is unable to find any such recitation. What applicant finds is that the claim recites that the collection is unique. However, the claim has since been extensively revised and hopefully eliminates all vagueness and is more easily understood. Applicant respectfully requests that the objection be withdrawn or clarified.

(19) Claim 15 is still further asserted to be vague and indefinite because it is asserted that the claim implies the use of a secondary antibody-enzyme conjugate, and that a primary antibody is not recited in the claim, making unclear to examiner whether a primary antibody is applied in the process. First, Examiner is referred to subparagraph (12), which discusses the same reasoning in connection with the recitations of claim 12, which is incorporated herein. Applicant requests the reasoning to be reconsidered and the rejection withdrawn.

Applicant believes that the foregoing amendment to the claims places the application in condition for allowance. Accordingly, an early notice of allowability is respectfully requested.

The lengthy and interesting patents and/or applications to McDevitt et al, Fritsh et al, and Macphee et al, cited of interest, were considered. However, those patents and applications do not appear to merit additional discussion.

CLAIM SUMMARY.

Claims 1-15 were in the application as filed. Claim 2 was cancelled, leaving claims 1 and 3-15 present for examination. Claim 8 formerly presented in dependent form has been rewritten in independent form.

ADDITIONAL CLAIM FEES

The number of claims as originally filed in total remains below twenty. The number of independent claims remains unchanged at four. Accordingly, no additional filing fee is due.

Applicant notes that the undersigned attorney is available by telephone to provide appropriate assistance to Examiner as will expedite the grant of the patent. So feel free to telephone.

Respectfully submitted:

Dated: April 30, 2004

By _____

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